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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/450,609	11/30/1999	HELLE WEIBEL	5739.200-US	7926

7590 12/31/2003

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EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 12/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/450,609	WEIBEL ET AL.	
	Examin r	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,7,9,12,13,16 and 28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,7,9,12,13,16 and 28* is/are rejected.

7)☒ Claim(s) *29-31* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 25, 2003 has been entered.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6, 7, 9, 12, 13, 16, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lohray et al.(WO 9741097).

Lohray et al. teaches at page 35, example, applicants' composition in a tablet form. Lohray et al. at page 34, lines 27-29, page 35, example, and page 7, lines 13-14, teach pharmaceutical composition containing applicants' active agent in tablet, capsule,

or powder form, in combination with the pharmaceutically acceptable excipient set forth in claim 6, and flavourants, sweeteners set forth in claim 16, and other media normally employed in preparing such compositions. Lohray et al. teach that the above composition typically contains from 1 to 20% by weight of active compound, and the reminder of the composition being pharmaceutically acceptable carrier, diluents or solvents. (page 35, lines 1-3).

Lohray et al. do not expressly teach the low water content comprising anhydrouse lactose and specifiec cellulose set forth in claim 6 and proportions of excipients set forth in claim 9.

It would have been obvious to one of ordinary skill in the art to modify Lohray composition to employ any form of lactose (e.g. anhydrose lactose) because Lohray et al. teach the composition comprising lactose in general. One would have been motivated to employ any form of lactose as taught by Lohray to provide a pharmaceutical composition containing the active agent for the effective treatment of diabetics because lactose as utilized in Lohray composition encompasses any lactose form including anhydrous lactose as claimed by the Applicants. The proportions of active agents to be used set forth in claim 9 and specified cellulose set forth in claim 6 are deemed obvious because it is within the knowledge of the skilled pharmacologist to optimize the range of amounts of active agents and the excipients to be utilized. Moreover, Lohray et al. teach the ranges of 1-20% as being an active compound and the remainder of the composition being pharmaceutically acceptable carriers, diluents or solvents. One of ordinary skill in the art would optimize this range of excipients within

the range of about 20-80% as taught by Lohray et al. Further, Lohray et al. utilize one of cellulose derivative (e.g. carboxymethyl cellulose) as useful excipient and have a viable utility as an excipient which is so closely related to microcrystalline cellulose utilized claimed by the Applicants and it is to be chemically obvious thereform (cellulose derivatives) in the absence of any unobvious or unexpected properties especially since one of ordinary skill in the art would expect that compounds so closely related chemically would have the same or essentially the same properties.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

Sohda reference is withdrawn as a reference in view of Applicants' amendment.

Allowable Subject Matter

Claims 29-31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicants arguments filed July 24, 2003 have been fully considered but they are not persuasive. Applicants argue that there is absolutely no suggestion or discussion in Lohray regarding the desirability of low water content in excipients and it would have not been obvious to consider using anhydrous lactose and/or cellulose with low water content. This is not persuasive because claim 6 is drawn to a pharmaceutical composition comprising the active agents and excipients such as anhydrous lactose, microcrystalline cellulose, magnesium stearate, and talc. The composition taught by Lohrey encompasses Applicants' composition set forth in claim 6 because as admitted by the Applicants that in the production of Lohray composition, the active ingredient and lactose are moistened or they were blended with water, therefore it would be likely that Lohray composition used the anhydrous lactose in order to moisten or blended the active compounds with water. Further, Lohrey composition comprises Lactose which encompasses Applicants' anhydrous lactose as well. Applicants' clarification of the Declaration filed with the response filed on August 23, 2002 is noted. However, formulations of A-B do not differ from the composition taught by Lohrey reference because Lohrey composition comprising Lactose encompasses anhydrous lactose. Applicants assert that the Sohda reference would not add anything further to the disclosure of Lohray and that Sohda et al. is directed to completely different class of compounds, 2,4-oxazolidinedione compounds. This argument is moot in view of Applicants' amendment to cancel claims 14 and 15, claims drawn to combination with anti-oxidants. For these reasons the claimed subject matter is deemed to fail to

patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 703-308-2232. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 703-305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
December 24, 2003

12/29/03